# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of LAKE et al.

Application No.

10/600,280

Group:

1744

Date Filed

June 20, 2003

Examiner

Jastrzab, Krisanne Marie

For: DECONTAMINATION DEVICE

# SUPPLEMENTAL APPEAL BRIEF UNDER 37 C.F.R. § 1.192

Mail Stop Appeal Brief - Patents Commissioner for Patents P.O. Box 1450 Arlington, VA 22313-1450

Sir:

This Supplemental Appeal Brief is being timely filed pursuant to the Notification of Non-Compliant Appeal Brief mailed November 24, 2006. subsequent to the filing of a Notice of Appeal, mailed December 16, 2005. No fee is believed due; however, the Commissioner for Patents is hereby authorized to charge any deficiency in fees to Deposit Account No. 50-0951.

## REAL PARTY IN INTEREST

The real parties in interest are Robert F. Lake, Jr. and Jeffrey S. Tenant, both of Boca Raton, Florida, who are the inventors of the subject Decontamination Device.

# RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to the Appellant.

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## STATUS OF CLAIMS

Claims 1-24 are pending in the application. Pursuant to 37 CFR §41.37(c)(1)(iii),

Applicants state that claims 1-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,722,537 to Sigler (hereinafter "Sigler") in view of U.S. Patent No. 5,641,464 to Briggs, III et al. (hereinafter "Briggs"). Accordingly, claims 1-24 are being appealed.

## STATUS OF AMENDMENTS

A response to the initial Office Action (dated March 16, 2005), was filed on June 29, 2005. A response dated November 16, 2005, was filed subsequent to the final rejection and included amendments to claims 1, 4, and 22. Pursuant to the Examiner's Advisory Action mailed November 23, 2005, these amendments were not entered.

## SUMMARY OF INVENTION

Applicants' pending claims are appended to this appeal brief, however, applicant would reiterate the limitations of the independent claims. Independent Claim 1 defines a decontamination device for decontaminating medical apparatus and requires:

- (i) a housing (pg. 3, par [0004], pg. 7 pars. [0022] and [0023], Figs. 1-2, item 14);
- (ii) an absorbent pad carrying a decontaminating compound within the housing (pg. 7, par. [0024], Figs. 1-2, item 18); and,
- (iii) structure for removably engaging the housing to a portion of the medical apparatus, whereby (a) the absorbent pad is placed into contact with a portion of the medical apparatus upon

engagement and (b) removed from contact upon disengagement (pg. 3, par. [0005], pgs. 7-8, par. [0025], Figs 1-2, item 44). As defined in Claim 2, this structure can be interlocking structure (pgs. 7-8, par. [0025], Fig. 2).

In claim 3, the structure for detachably engaging the housing to the medical apparatus can be elastically deformable "snap-on" structure for engaging a portion of the medical apparatus (pg. 3, par. [0005], pgs. 7-8, par. [0025], Figs 1-2, item 44). In claim 4, the snap-on structure can be an elastically deformable, inwardly directed protrusion on the housing which fits around a portion of the medical apparatus when that portion is placed into the housing (Fig. 2, item 44). An interlock with the housing results (Claim 24).

The dispenser can include suitable structure for dispensing the decontaminating compound onto the portion of the medical apparatus within the housing. In one embodiment, the dispenser comprises an absorbent material having absorbed therein the decontaminating compound (Claim 1, pg. 7, par. [0024], Figs. 1-2, item 18). The absorbent material stores and releases the decontaminating compound onto the surface of the medical apparatus when the medical apparatus contacts the absorbent material.

As claimed in claims 5-6, the decontamination device can have structure for attaching the decontamination device to the medical apparatus when the medical apparatus is in use, to prevent the decontamination device from being separated from the medical apparatus. The attachment structure can be a lanyard (pgs. 8-9, par. [0029], Fig. 5, item 74).

Packaging for the decontamination device can be provided. A removable cover can be provided for the housing (Claim 7, pg. 8, par. [0028], Fig. 3, item 30 and Fig. 4, item 62). At least two of the decontamination devices can be detachably engaged (Claim 8, pg. 8, par. [0028], Fig. 4, item 58).

The housing can comprise indicia for providing information about the decontamination device (Claims 9-11, pg. 9, par. [0030], Fig. 6, item 88). The indicia can comprise at least one selected from the group consisting of color, printed material, and embossed material (Claim 10). The indicia can indicate at least one selected from the group consisting of the decontamination compound and the particular medical apparatus for which the sterilization device is intended (Claim 11).

The decontamination compound can be any suitable decontaminating compound.

Suitable decontamination compounds include, but are not limited to the group consisting of: glutaraldehydes, such as 2% alkaline glutaraldehyde, glutaraldehyde-phenate; chlorine compounds, such as sodium hypochlorite and calcium hypochlorite; alcohols, such as 70-99% isopropyl or ethyl alcohol; iodophors, such as providone-iodine; peroxygen compounds, such as 3% stabilized hydrogen peroxide; phenolics, such as derivatives of phenol; and quaternary ammonium compounds, such as benzalkonium chloride (Claims 12-19, pg. 8, par. [0026]).

The device can contain an indicator compound for indicating that the medical apparatus has been decontaminated by the decontamination device. The indicator compound can be a dye, colorant, chemical marker, or radioisotope (Claim 20, pg. 9, par. [0031]).

The decontamination device can be adapted for use with a stethoscope. In this embodiment, the housing is dimensioned so as to receive at least a portion of the head of the stethoscope (Claim 21, pg. 7, par [0025], Fig. 2)).

A method is provided for utilizing medical apparatus. A decontamination device is provided with a housing and a dispenser within the housing for contacting a portion of the medical apparatus with a decontaminating compound when the portion of the medical apparatus is placed within the housing, and structure for removably engaging the housing to the medical

apparatus. A portion of the medical apparatus is placed within the housing and in contact with the dispenser. The decontaminating compound from the dispenser contacts a portion of the medical apparatus, thereby decontaminating that portion. The medical apparatus is then used, and after use is placed again into the decontamination device and engaged to the decontamination device (Claims 22-23).

## ISSUES PRESENTED FOR REVIEW

Whether claims 1-24 are patentable under 35 U.S.C. § 103 over Sigler in view of Briggs.

#### ARGUMENT

Claims 1-24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sigler in view of Briggs. Applicants' submit that the Examiner has misconstrued Applicants' claims, as defined by both the specification and the ordinary meaning of these terms to one having skill in the art. Applicants' claims, properly construed, define structure nowhere shown or suggested by the cited references, either alone or in combination. The Examiner has thereby misapplied the cited references to Applicants' claims.

Applicants' intend to demonstrate in this brief that the claimed features, taken as a whole, are not shown or suggested in the references cited by the Examiner. Most notably, Applicants' intend to demonstrate that the references do no show the engaging of the medical apparatus to the housing as such term would be interpreted from this specification, or from the ordinary meaning of the term, by one skilled in the art. The references similarly do not show or suggest the claimed method, and more specifically the engagement of the medical apparatus to the

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housing in a manner which both engages the medical device to the housing and contacts at least a portion of the medical device to a dispenser containing the decontaminating compound.

# A. The Briggs Reference

Briggs discloses a stethoscope cleaning device and method in which a stethoscope head 27 is positioned in space 13 on drip plate 14. The stethoscope head 27 is not engaged by the housing 10, but rather rests within the housing 10. The flexible, resilient closeable X-shaped or iris-shaped diaphragm 60 includes a port 25. The flexible diaphragm 60 is identified by Briggs exclusively for flexibly sealing around the medical device, in the nature of a drape, to prevent the egress of aerosol spray from canister 15. Briggs, column 3, lines 29-36.

# B. The Sigler Reference

Sigler discloses a portable disinfectant container for an infant pacifier or infant nursing nipple. A container 17 has an immovable lid portion 3 and another lid portion 2 attached by a conventional hinge. A fastener 4 has a stem 18 with a hook portion 19 to attach the device to a purse, etc. Sigler, column 2, lines 39-49. A sponge 10 is provided in the container and has a slit 11 to receive a pacifier or nursing nipple for sterilization. The "shape of the opening or slit 11 is not critical, and the opening could be of any shape which will allow a nipple or pacifier, or similar item to be pushed into the sponge 11 and sterilized." Sigler, column 3, lines 1-7 (emphasis added). There is no mention of engagement between the pacifier and the disinfectant container housing 17.

## C. Deficiencies of the Cited References.

The Briggs reference is fundamentally different from Applicants' invention. It is essentially a spray booth for an aerosol disinfectant. The flexibility of the diaphragm and the

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size of the port 25 as visible in Fig. 2 of Briggs cannot engage the stethoscope as required by Applicants' claims. The term "flexible" by definition requires yielding. A yielding structure cannot engage a device against motion. Should the diaphragm 60 of Briggs be of a sufficient rigidity that it would engage the housing and the medical apparatus, it would not flexibly seal around the tube 28 of stethoscope 58, as intended by Briggs, to guard against the egress of aerosol spray. The provision of the open port 25 with no engagement structure at its edge would also serve to prevent engagement with the stethoscope.

Claim 1 of Applicants' invention defines an absorbent pad carrying a decontaminating compound as distinguished from a spray canister such as used in Briggs. In Applicants' device, the housing holds the absorbent pad within its structure and positively engages the absorbent pad against a portion of the medical apparatus (stethoscope head) whereby the absorbent pad is placed into direct contact with the portion of said medical apparatus; then removed from contact upon disengagement (Figs. 1-2). Thus, the housing has structure associated therewith so the stethoscope head is forced into contact with the absorbent pad and then released as the stethoscope head is withdrawn with force from the housing upon disengagement. Briggs lacks an absorbent pad carrying a decontaminating compound as well as structure for removably engaging said housing with respect to a portion of said medical apparatus whereby said absorbent pad is placed into contact with said portion of said medical apparatus upon engagement and removed from contact upon disengagement. Briggs does not disclose or suggest Applicants' invention.

Claim 2 calls for interlocking structure for engaging a portion of said medical apparatus which is completely absent from Briggs. The interlocking structure securely retains the medical device, which the Briggs device would not.

Claim 3 defines the interlocking structure as an elastically deformable, inwardly directed protrusion on said housing. Once again, such structure is completely lacking in Briggs. The flexible diaphragm 60 of Briggs cannot in any ordinary sense be read to interlock with the medical device.

With respect to claims 5-6, claim 5 defines structure for attaching the medical device to the decontamination device when the medical device is in use. In claim 6 this structure is defined as a lanyard. This points out one of the advantages of Applicants' device, which is that when connected by a lanyard to the medical device such as stethoscope tubing, the decontamination device can hang from the stethoscope tubing and be ready for use. It cannot be inadvertently misplaced. Nothing like this is contemplated by Briggs. In fact, the stethoscope must be put down by a medical professional as the stethoscope head is placed into the Briggs chamber. No mention is made of disinfecting the stethoscope head while being carried around the neck of a doctor and any reasonable interpretation of Briggs would indicate that this is not possible.

Claims 12-19 calls for particular decontaminating compounds in combination with an absorbent pad that is engaged to the medical device. Briggs does not have an absorbent pad.

Sigler discloses a portable disinfecting container for an infant's pacifier. As such, it is non-analogous art and should not have been cited in the first instance (MPEP 2141.01(a)). To rely on a reference under 35 U.S.C. § 103, it must be analogous prior art:

The Examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be

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reasonably pertinent to the particular problem with which the inventor was concerned." In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also In re Deminski, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); In re Clay, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem."); and Wang Laboratories Inc. v. Toshiba Corp., 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993).

The Sigler reference would not be considered by one skilled in the art to be pertinent to the problem solved by the invention. There is no mention in Sigler of any medical applications of this device, and it does not solve the problem of how to insure that users will use the decontamination device frequently and as necessary, which was solved in the invention by directly engaging or interlocking the decontamination device to the medical apparatus in such a way that the engaging act itself results in decontamination, and the decontamination device stays engaged with the medical device until use, thereby preventing accidental contamination.

Assuming, arguendo, that Sigler is citable it does not disclose or suggest Applicants' invention. Sigler does not disclose engaging (claim 1) or interlocking (claim 3) of the decontamination device with the medical apparatus. In fact, Sigler teaches no relative engagement between the pacifier or nipple and the disinfectant container at all. Rather, the device is used to "dip the nipple inside the disinfectant-filled sponge 10, remove it and then replace lid 2 to prevent the liquid from drying out." Sigler, column 3, lines 63-65. Also, at column 2, lines 6-14, Sigler states:

When an infant drops a pacifier or nursing bottle on the ground, the disinfecting container lid is opened, the pacifier or nipple is inserted into the center slit of the absorptive sponge, and the pacifier or nipple is moved in an up and down motion, a sideways motion, or a circular motion so as to have all surfaces of the pacifier or nipple come into contact with the disinfecting liquid which has been absorbed by the sponge.

There is no disclosure or suggestion whatsoever in Sigler of an engagement or interlocking between the container 17 of Sigler and the nipple as defined in claims 1-2. An examination of Sigler would indicate that such an engagement is not possible. The lid 2 of Sigler is connected such that, when opened, it is orthogonal to the rest of the device. This would block any engagement between the pacifier and the device. The presence of the stem 18 would similarly block engagement. Indeed, as the above passage indicates, no engagement is contemplated. The above argument applies equally to the application of Briggs and Sigler to method claims 22-23, which claims also require engagement.

The Examiner states, speaking of Sigler, "The device is provided with hook or lanyard means to connect it to the Pacitizer even when not in use." Sigler, in describing Fig. 1, states "spring-biased fastener 4 when it is desired to attach The Pacitizer 1 to a purse, baby bag, stroller, crib etc." Also, in Fig. 3 the biased hook 4 is replaced with an eyelet-type fastener 12 contemplating straps 14, such that the straps can be attached to a crib rail, stroller handle or other large article. There is no mention that the hook 4 or straps 14 will be connected to the pacifier itself. Accordingly, there is no teaching of attaching a lanyard from Applicants' decontamination device to the medical apparatus (stethoscope) itself such that they do not become separated (Claims 5-6).

D. The Combination of the References, if the References are Combinable, Does Not Reach the Invention

Neither Briggs or Sigler teach "structure for removably engaging said housing to a portion of said medical apparatus" (Claim 1), and further do not disclose a device wherein "said structure for removably engaging said housing to said medical apparatus comprises interlocking structure for engaging a portion of said medical apparatus." (Claim 2) The definition of "engage" is "to interlock with." Merriam-Webster Online, www.m-w.com/dictionary/engage. Further, the definition of "interlock" is "to lock together:UNITE". Merriam-Webster Online, www.m-w.com/dictionary/interlock. That this ordinary meaning of the term was intended and would be applied by one skilled in the art is apparent from the specification, where it is clear that the two pieces are connected together in a "locked" fashion (pgs. 7-8, par. [0025], Fig. 2). The Examiner's conclusion that the combination of Briggs and Sigler yields such an engagement is simply incorrect given any reasonable interpretation of the terms "engaged" or "interlocked" in light of the specification, which teaches as follows:

[0005] The structure for detachably engaging the housing to the medical apparatus can be snap-on structure for engaging a portion of the medical apparatus. The snap-on structure can be elastically deformable, inwardly directed protrusion on the housing which fits around a portion of the medical apparatus when that portion is placed into the housing.

\* \* \*

[0025] The structure for engaging a portion of the medical apparatus can be any suitable structure. This can include cooperating tongue and groove structure, slots, snaps, fasteners, and other engagement structure. In the embodiment shown

in Fig. 2, an inwardly directed protrusion 44 is formed in the housing 14. The housing 14 has suitable flexibility to permit flexing when the medical apparatus, such as a stethoscope head 36 contacts the protrusion 44. The head 36 will then interlock with the housing 14 as shown in Fig. 2.

"Detachably" necessarily requires "attaching". By either intrinsic or extrinsic measures, the references do not reach what Applicants' describe as "engaging" or "interlocking". Fig. 2 of the drawings clearly illustrates an example of what the Applicants' were referring to by the terms "engaging" and "interlocking". This structure is nowhere shown or suggested by Sigler or Briggs et al. If neither reference discloses "engagement" or "interlocking" within the meaning of the specification and the ordinary meaning of these terms, the combination also cannot reach Applicants' invention.

The specification is the primary basis for construing the claims and "the ordinary and customary meaning" of claim language as understood by a person of skill in the art is the definition of importance. The Examiner concedes that such person is in "the field of endeavor...directed to point of use sterilization/disinfection of objects subject to human contact which can transmit bacterial contamination." Office Action mailed 9/16/2005, page 5. Yet, the Examiner maintains, this hypothetical person, concerned with bacterial infection, would view the disclosure of either Sigler or Briggs as teaching engaging the medical device so as to guard against the continued threat of bacterial infection? Where is the motivation in Briggs to engage the medical device in such a manner that the decontamination device would remain connected to the medical device until use? Not in Briggs, and not in Sigler either. Sigler says absolutely nothing about any engagement, let alone engagement that would secure the medical device to the Briggs device. Briggs merely drapes a flexible curtain over the medical device. Is this the sort

of "engagement" that one skilled in the art of disinfection would rely on to guard against bacterial infection? The answer must be in the negative.

With respect to Applicants' claims 5 and 6, i.e., the additional means for attaching which is described as a lanyard. The attachment means of Sigler 4, 14 is for attaching the decontamination device to some other physical article and not the object to be disinfected, i.e., Applicants' medical apparatus, i.e., stethoscope. Briggs and Sigler totally fail to describe such a feature.

Neither reference discloses an indicator compound (Claim 20) for indicating that the apparatus has contacted the medical device. This is a significant feature as it provides a positive indication that the medical device has been sterilized. This advantage is not available from Briggs or Sigler.

Claim 21 claims the decontamination device of claim 1 wherein said housing is dimensioned to receive the head of a stethoscope. Combined with the removable engagement and disengagement language of claim 1, claim 21 points out the need for a positive engagement of a stethoscope head within the housing to force it into engagement with the absorbent pad. Briggs and Sigler have no interest in the precise size of the stethoscope head or the size of the pacifier as long as the containers were big enough to receive such objects. This is because in neither case is the positive engaging structure important so that a proper engagement occurs to assure decontamination. Rather, in Briggs and Sigler it is just a case of placing the items to be decontaminated, loosely, in the respective decontamination containers, but without engagement. Sigler requires movement of the pacifier within the device by the user in order to effect decontamination. Such movement is not required by the subject invention.

Finally, the method of claims 22-23 is clearly distinguishable over any possible combination of Briggs and Sigler. Neither reference suggests a decontamination device that is engaged to the medical device (such as a stethoscope) to be decontaminated, where the engagement contacts the medical device with the dispenser and a decontaminating compound. The method of Briggs is to place the medical device into the cleansing device and then operate the aerosol canister 15 to effect disinfection. The medical device never touches the dispenser 15, and Briggs provides no teaching of how such would be accomplished. Sigler discloses a process in which the pacifier is inserted into the slit 11 and "moved in an up and down motion, a sideways motion, or a circular motion." Sigler, Col. 2, lines 8-10. There is no disclosure of engagement of the pacifier to the container 17 as a part of Sigler's method. Indeed, the hinged lid portion 2 abuts the stem 18 and would block any engagement of the pacifier. In neither Sigler nor Briggs is there any hint of positively engaging an absorbent pad against the head of a medical device such as a stethoscope by engagement structure associated with the housing of the absorbent pad. The references fail singularly, or in combination, to yield the inventive concept of Applicants' invention.

## CONCLUSION

The references of record do not disclose or suggest a decontamination device which is capable of secure engagement to or interlocking with a medical apparatus in a manner to prevent inadventent contamination, and where the mere act of engaging causes the medical device to be sterilized. The subject invention permits the decontamination device to be carried with the medical apparatus in a manner not available with the references of record.

Accordingly, Appellants submit that the claimed device, as defined in claims 1-24, is not rendered obvious under 35 U.S.C. § 103(a) by the Sigler or Briggs references, either singly or in

combination. It is thus submitted that claims 1-24 define a patentably distinguishable invention over the prior art made of record, and a Notice of Allowance for claims 1-24 is respectfully requested.

Respectfully submitted,

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## APPENDIX

The claims involved in the appeal are indicated below and show the proposed amendments as filed in the Response dated June 29, 2005:

- A decontamination device for decontaminating medical apparatus, comprising:
   a housing:
- an absorbent pad carrying a decontaminating compound placed within said housing; and structure for removably engaging said housing to a portion of said medical apparatus, whereby said absorbent pad is placed into contact with said portion of said medical apparatus upon engagement and removed from contact upon disengagement.
- The decontamination device of claim 1, wherein said structure for removably
  engaging said housing to said medical apparatus comprises interlocking structure for engaging a
  portion of said medical apparatus.
- The decontamination device of claim 2, wherein said interlocking structure comprises at least one elastically deformable, inwardly directed protrusion on said housing.
- The decontamination device of claim 1, wherein said housing comprises absorbent pad and a flexible portion to facilitate the removable engagement to said medical instrumentation.
- The decontamination device of claim 1, further comprising additional means for attaching said housing to said medical apparatus.
- The decontamination device of claim 5, wherein said additional means is a lanyard.
- The decontamination device of claim 1, further comprising a removable cover for said housing.

- The decontamination device of claim 1, wherein at least two of said housings are detachably engaged.
- The decontamination device of claim 1, wherein said housing comprises indicia providing information concerning said decontamination device.
- The decontamination device of claim 9, wherein said indicia comprises at least one selected from the group consisting of color, printed material, bar code, and embossed material.
- 11. The decontamination device of claim 9, wherein said indicia comprises at least one selected from the group consisting of the decontaminating compound and the medical apparatus for which the decontamination device is intended.
- The decontamination device of claim 1, wherein said decontaminating compound comprises a disinfecting compound and a sterilizing compound.
- The decontamination device of claim 1, wherein said decontaminating compound is at least one selected from the group consisting of glutaraldehydes.
- 14. The decontamination device of claim 1, wherein said decontaminating compound is at least one selected from the group consisting of chlorine compounds.
- 15. The decontamination device of claim 1, wherein said decontaminating compound is at least one selected from the group consisting of alcohols.
- 16. The decontamination device of claim 1, wherein said decontaminating compound is at least one selected from the group consisting of iodophors.

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- The decontamination device of claim 1, wherein said decontaminating compound is at least one selected from the group consisting of peroxygen compounds.
- 18. The decontamination device of claim 1, wherein said decontaminating compound is at least one selected from the group consisting of phenolics.
- The decontamination device of claim 1, wherein said decontaminating compound
  is at least one selected from the group consisting of quaternary ammonium compounds.
- 20. The decontamination device of claim 1, wherein said dispenser contains an indicator compound for indicating that the medical apparatus has been contacted by said decontaminating compound.
- The decontamination device of claim 1, wherein said housing is dimensioned to receive the head of a stethoscope.
- 22. A method for using medical apparatus, comprising the steps of: providing a decontamination device comprising a housing, a dispenser within said housing for contacting a portion of said medical apparatus with a decontaminating compound when said portion of said medical apparatus is placed within said housing, and structure for removably engaging said housing to said medical apparatus;

placing a portion of said medical apparatus in said housing, thereby contacting said portion with said dispenser and said decontaminating compound;

removing the portion of said medical apparatus from said housing; using the medical apparatus in furtherance of medical procedures;

replacing the portion of the medical apparatus in the housing of the decontamination device and engaging the housing to the medical apparatus using said, engagement structure, whereby said portion of said medical apparatus is again decontaminated; and

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engaging said decontamination device with said medical apparatus during the decontamination step and the medical use step.

- 23. The method of claim 22, wherein said decontaminating compound is comprised of at least one of a sterilizing compound and a disinfecting compound.
- 24. The decontamination device of claim 4 wherein said housing further comprises an inwardly directed protrusion to which when combined with the flexible portion causes an interlock of the housing with the portion of said medical apparatus.